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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,479	07/23/2004	Patrick Wuthrich	SERVIER 427 PCT	4008

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EXAMINER	
MERCIER, MELISSA S	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
11/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,479	WUTHRICH ET AL.	
	Examiner	Art Unit	
	MELISSA S. MERCIER	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-16 and 18-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-16, 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of Applicants Remarks and Amended Claims filed on July 7, 2009 and the Response to the Non-Compliant Amendment filed on August 31, 2009 is acknowledged. Claims 10-16 and 18-21 remain pending in this application.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

It is further acknowledged that Applicant has filed a certified English translation of the foreign priority documents on July 23, 2004.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

The rejection of claim 14 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of Applicants Amendment to the claim limiting the "Flow Agent" to colloidal silica.

The additional rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention specifically, because it was unclear if applicant is claiming one or more lubricants OR flow agents or one or more lubricants AND flow

agents, has been withdrawn in view of Applicants amendment to the claim clarifying the claim language with appropriate punctuation.

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-15 and 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luhn (US 6,770,368) in view of Wikipedia Perindopril Product Information Disclosure.

Luhn teaches using granules consisting of lactose and starch (col. 2, lines 38). Example 2 discloses numerous examples of starch/lactose tablets having hardness factors with the ranges claimed in instant claims 19-20, which dissolve in less than 3 minutes and preferably less than 1 minute as recited in claims 12-13. If a lower hardness was desired one of ordinary skill in the art would be motivated to modify the ratio of lactose to starch to achieve the desired hardness and it would be obvious to optimize the formulation through routine experimentation to achieve a tablet with the desired hardness.

Regarding claim 16, in part, Example 2 additionally discloses the tablets tested comprise magnesium stearate, which is a lubricant.

Regarding claims 17-18, Luhn discloses tablets made with the co dried granules (column 3, lines 64-68) using an AM type Frogerais alternating press which uses direct compression.

The granules can be used in pharmaceutical preparations (col. 3, line 44). Luhn teaches the generically that the granules can be used in pharmaceutical formulations. One of ordinary skill in the art would be motivated to look to the prior art for suggestions of active ingredients to use in making a rapidly dissolving tablet.

Luhn does not disclose the specific use of perindopril.

Wikipedia discloses perindopril is used as an ACE inhibitor and is commonly administered in dosages of 2-10mgs for the treatment of high blood pressure.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have used co-dried starch and lactose granules to make a tablet for pharmaceutical use because Luhn teaches the granules impart reduced friability, efficient flow, good tabletting capacity and satisfactory disintegrating properties (col. 2, lines 30-35). One of ordinary skill in the art at the time the invention was made would have been motivated to use any pharmaceutical in a tablet formulation exhibiting satisfactory disintegrating properties especially when it is desired for the pharmaceutical to be delivered rapidly in order for the therapeutic effect to quickly take affect. One of ordinary skill in the art would be motivated to use perindopril in the pharmaceutical dosage form because it is effective for reducing blood pressure.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues:

Luhn does not disclose the disintegration properties of the instant claims.

While the Examiner has acknowledged the prior art is silent to this particular functional property, however, after further review, since the prior art discloses the same lactose/starch granules as the instant claims, within the same ratio and tablets having a hardness within the claimed range, it is the position of the examiner that such a functional property would necessarily also be present. The burden is on Applicant to show that the functional property would not be present. Arguments of counsel do not take the place of evidence when evidence is needed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-16 and 18-21 of copending Application No. 10/502,593. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only differences between the two applications are the active agent. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted any active agent into the formulation in order to obtain the desired therapeutic benefits.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-18 and 20-23 of copending Application No. 10/502,594. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only differences between the two applications are the active agent. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted any active agent into the formulation in order to obtain the desired therapeutic benefits.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11-23 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 7,201,922. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only differences between the two applications are the active agent. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted any active agent and to optimize the percentage of the active agent in the formulation in order to obtain the desired therapeutic benefits.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues:

*the active agents are distinct with distinct pharmacological activity, side effects, and interaction profiles and one of ordinary skill would not expect to rely on any degree of certainty on such prior art teachings in optimizing a formula disclosed in the instant applications.

While the Examiner concedes that the active agents are different, it would have been obvious to the skilled artisan to use any active agent in order obtain the benefits of the lactose/starch granules, including impart reduced friability, efficient flow, good tabletting capacity and satisfactory disintegrating properties (col. 2, lines 30-35). One of ordinary skill in the art at the time the invention was made would have been motivated to use any pharmaceutical in a tablet formulation exhibiting satisfactory disintegrating

properties especially when it is desired for the pharmaceutical to be delivered rapidly in order for the therapeutic effect to quickly take affect.

Newly Applied Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Luhn (US 6,770,368) in view of Dobetti (US Patent 6,596,311) and further in view of Wikipedia Perindopril Product Information Disclosure.

The combined teachings of Luhn in view of the Wikipedia disclosure are discussed above and applied in the same manner.

Luhn does not disclose the use of colloidal silica in his composition.

Dobetti discloses fast disintegrating tablets comprising magnesium stearate as a lubricant and colloidal silica as a glidant (column 5, lines 45-68).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a glidant in the granulation because Dobetti discloses that superior tabletting properties can be achieved by choosing appropriate amounts of ingredients, such as lubricants and glidant.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615